U.S. Environmental Protection Agency
Office of Research and Development

BOARD OF SCIENTIFIC COUNSELORS
DRINKING WATER RESEARCH SUBCOMMITTEE
Program Review Meeting Summary
June 21-23, 2005
Cincinnati, OH

Tuesday, June 21, 2005

WELCOME AND INTRODUCTION
Dr. Gary Sayler, Chair, Drinking Water Research Subcommittee

Dr. Gary Sayler, Chair of the Board of Scientific Counselors (BOSC) Drinking Water Research Subcommittee, welcomed the participants to the meeting. The Subcommittee members introduced themselves: Drs. Mary Ward, David Sedlak, James Johnson, James Raymer, Selene Chou, and Designated Federal Officer (DFO) Ms. Edith Coates.

DFO WELCOME AND CHARGE
Ms. Edith Coates, DFO, Drinking Water Research Subcommittee, EPA

Ms. Coates explained that the Subcommittee has had two teleconferences, one administrative and one technical. Another teleconference might take place in July or August to finalize the report. This meeting includes U.S. Environmental Protection Agency (EPA) presentations and posters, Subcommittee questions and group discussion, and the opportunity for public comment. No requests have been made for public comment; however, time will be available at the end of the meeting for anyone wishing to make a public comment. Ms. Coates explained that meeting minutes were being taken and, to improve their accuracy, she asked the participants to identify themselves before speaking.

The Subcommittee's objective is to evaluate the relevance, quality, performance, and scientific leadership of the Office of Research and Development's (ORD) Drinking Water Research Program (DWRP). The panel's evaluation and recommendations will help ORD plan, implement, and strengthen the program; compare the program with similar programs in EPA and other agencies; make research investment decisions over the next 5 years; prepare EPA's performance and accountability reports to Congress under the Government Performance Results Act (GPRA); and respond to evaluations of federal research, such as those conducted by the Office of Management and Budget (OMB).

Ms. Coates presented the guidelines for this federal advisory committee meeting. She explained that for a BOSC Subcommittee meeting, EPA staff was there to provide technical information to the Subcommittee, as requested by the members, during the presentations. EPA staff must go

through Ms. Coates to distribute any new information to the Subcommittee. In addition, EPA staff members do not ask questions of the Subcommittee or give opinions on their deliberations, whether oral or written. The EPA presenters interact only with members of the Subcommittee and invoke assistance from other EPA staff for clarification or for additional information only, with the agreement of the BOSC Subcommittee Chair.

Dr. Sayler thanked the EPA staff on behalf of the Subcommittee for preparing the meeting materials, and expressed his appreciation for the time and effort involved.

ORD WELCOME
Dr. William Farland, Acting Deputy Assistant Administrator for Science, ORD, EPA

On behalf of himself and Mr. Timothy Oppelt, Acting Assistant Administrator for ORD, Dr. William Farland welcomed the Subcommittee members and expressed appreciation for their efforts. He explained that this review meeting is a BOSC function, under the leadership of Drs. Sayler and Johnson, and the fifth program review conducted since December. He welcomed colleagues from Cincinnati and the program offices, notably the Office of Water (OW), as well as representatives from the regional offices, the states, and the public.

Dr. Farland emphasized the importance of a transparent dialogue. He reiterated that the program reviews focus on the quality and relevance of ORD's work and the ability to demonstrate leadership in a field of science that is responsive to the Agency's mission. EPA's work is focused on outcomes—protecting human health and the environment. It addresses questions that the programs pose while meeting regulatory mandates, and it anticipates and prepares for future issues.

National Program Directors (NPDs) were established to provide scientific leadership. Dr. Farland acknowledged Dr. Gregory Sayles, Acting NPD for Drinking Water, and expressed appreciation to him and his team for their work on this program review. For the past several years, the DWRP has focused on identifying outcomes (i.e., ways that science informs decisionmaking, enhances public health, or protects the environment). The program is a mix of basic and applied work. That balance should be kept in mind while anticipating upcoming problems, applying new technologies, and performing other activities.

The DWRP is aligned closely with the regulatory needs and schedule of a program office; this feature is unique and productive in providing scientific support that leads to environmental outcomes. Dr. Farland emphasized the importance of this review and encouraged the Subcommittee to prepare a forthright report.

Dr. Sayler commented that the BOSC is aware of the importance of OMB's Program Assessment Rating Tool (PART) process. He added that there are distinct differences between outputs and outcomes. He stressed that ORD needs to focus on outcomes. The Subcommittee members will keep this in mind during the review.

INTRODUCTION TO THE DRINKING WATER RESEARCH PROGRAM

Ms. Sally Gutierrez, Acting Laboratory Director, National Risk Management Research Laboratory (NRMRL), ORD, EPA

Ms. Sally Gutierrez outlined her presentation, which included a discussion of peer reviews, the Subcommittee's charge, the logic model, background on water research, and an overview of the Subcommittee meeting.

Peer Reviews

The National Academy of Sciences (NAS) recommended an independent expert review of federal research programs to develop objective information about their performance and to provide guidance for strengthening them. OMB has reinforced the importance of independent expert review. ORD is committed to independent review of its programs. The U.S. Office of Science and Technology Policy/OMB investment criteria for federal research programs requires programs to be relevant to national priorities, Agency issues, and customer needs. Ms. Gutierrez emphasized the importance of setting goals and demonstrating progress to maximize the quality of the research. She added that the Subcommittee's recommendations will be considered seriously. The results of this review will be used to verify clients' use of the research results to strengthen the Agency's environmental decisionmaking. In addition, the Subcommittee's recommendations will help determine research investments and disinvestments and prepare the program for the GPRA reporting and the OMB PART assessment.

Subcommittee's Charge

The Subcommittee's charge is to review the relevance, design, progress, quality, scientific leadership, and communication of ORD's DWRP. The Subcommittee also was asked to evaluate the program to date, provide guidance for future directions and plans, and guidance for the PART review.

In evaluating relevance, the Subcommittee should determine whether: (1) the program is responsive to the Agency's strategic goal for clean and safe water; (2) the potential public health benefits of the program are clearly evident; and (3) the program leverages its efforts with internal and external parties to study high-impact environmental questions.

In terms of the DWRP design, the Subcommittee should determine whether: (1) the program design is logical; (2) the goals and priorities are identified clearly; (3) the multi-year plan (MYP) describes an appropriate flow of work that reflects the anticipated pace of scientific progress and the timing of projects to meet clients' needs; and (4) the long-term goals (LTGs) within the MYP provide a logical framework for planning the research and demonstrating outcomes.

In evaluating progress, the Subcommittee should determine whether: (1) significant progress has been made toward each LTG; (2) key scientific questions have been addressed; (3) the rationale for the research is articulated clearly; (4) the program has met client needs in a timely and useful way; (5) the clients have applied the research in environmental decisions and regulations; and

(6) the program has been successful in providing technical assistance to OW, states, regions, and the water industry.

In assessing the program's quality, the Subcommittee should: (1) evaluate the quality of the research products; (2) determine whether funds are allocated to the highest priority needs; and (3) examine the process used to ensure that quality is maintained.

In evaluating the DWRP's scientific leadership, the Subcommittee should ask whether: (1) the program has played a leadership role in advancing the state-of-the-science and solving important drinking water research issues; (2) ORD scientists have demonstrated leadership in the field of drinking water research; and (3) the products are of high impact to the industry.

In terms of coordination and communication, the Subcommittee should determine: (1) whether the program has engaged scientists and managers from ORD and OW in its planning; (2) whether the key research gaps have been identified and the research agenda has been updated with input from the scientific community and stakeholders; (3) the extent to which other agencies are used to advance EPA's research agenda; (4) whether internal and external collaboration is demonstrated (i.e., multidisciplinary strengths are being used); and (5) whether the program uses effective mechanisms to communicate research activities and results, both internally and externally.

Logic Model

ORD is promoting the logic model as a tool to identify relevant short-term and long-term research outcomes of the DWRP. The logic model also demonstrates links between ORD's research activities and EPA's mission. This has been a challenge to the program.

Research programs produce information that helps the Agency make decisions, and the decisions help resolve problems. For the DWRP, EPA's mission is to reduce microbes, chemicals, and/or radiological materials in drinking water. The logic model presents resources, activities, outputs, clients, and clients' use of outputs. These lead to outcomes, which lead to risk reduction and public health protection. Dr. Sayles will explain this in more detail during his presentation.

Water Research

Water research has been conducted in Cincinnati for nearly a century. Before EPA was formed, Congress considered establishing a water research center in Cincinnati. In 1975, President Ford established the Andrew B. Breidenbach Environmental Research Center (in which this meeting took place) to further the research and maintain a stable presence.

Through the years, the DWRP has addressed many issues, including disinfection byproduct (DBP) control, DBP identification, and homeland security. Ms. Gutierrez showed a map of the states that are anticipated to exceed the new arsenic maximum contaminant level (MCL) for drinking water. Thousands of small water systems are affected by this rule, which has been a challenge.

Ms. Gutierrez explained that environmental problems remain despite the fact that EPA has promulgated regulations. For example, even with strong regulations, the Washington, DC, area has ongoing problems with lead in its drinking water. Drinking water is an issue that is of great concern to the public. In the Columbus, Ohio, area, atrazine found in the drinking water caused a public outcry. The DWRP's goal is to elucidate the uncertainties associated with these problems. The framework that Congress provided for the Safe Drinking Water Act (SDWA) perpetuates a need for additional information.

ORD is starting to look at drinking water protection from a holistic viewpoint, which includes source water protection, treatment, management of residuals from treatment processes, distribution characterization, and compliance monitoring, all of which lead to health benefits. ORD's drinking water research influences each of these areas. The DWRP has been active in:

- ✧ Selecting contaminants
- ✧ Determining occurrence
- ✧ Developing monitoring methods
- ✧ Determining health effects
- ✧ Conducting risk assessments
- ✧ Developing cost models
- ✧ Conducting treatability studies
- ✧ Researching distribution system effects
- ✧ Evaluating implementation issues
- ✧ Conducting the 6-year review
- ✧ Supporting water security
- ✧ Studying outcomes.

In addition, Dr. Rebecca Calderon is working on a new part of the program that studies the consequences of filtration stops and starts and the effect on public health. This work also examines whether public health can be quantified.

Meeting Outline

Ms. Gutierrez reviewed the DWRP Subcommittee meeting agenda. Dr. Sayles will provide an overview of the program's structure, LTGs, scientific questions, relevance, and design. Dr. James Goodrich will present an overview of LTG 1 (i.e., regulated contaminants in drinking water and the impacts of the research). A poster session and discussion will follow. Dr. Fred Hauchman will speak about unregulated contaminants (LTG 2). Another poster session and discussion will follow. Presentations from ORD clients will include Mr. Anthony Bennett, a state regulator; Mr. Kim Fox, National Homeland Security Research Center; and Mr. Richard Karlin, American Water Works Association Research Foundation (AwwaRF). The presentations are intentionally brief; the poster sessions will provide more depth. The presenters include scientists from ORD laboratories and centers. The principal investigators will provide more detailed descriptions of the research. The posters are aggregates of a body of research, and they include the work of a number of Science to Achieve Results (STAR) grantees. The discussions following the poster sessions will allow the Subcommittee to meet collectively with the principal investigators, provide additional information to address questions or clarify issues, and organize thoughts on the body of research presented.

Questions and Answers

Dr. Sayler asked about the topic of source protection. Ms. Gutierrez explained that it is part of the program, although not a large part. Current studies are trying to characterize watershed landscapes as they relate to contaminants that can be controlled at a watershed level. The DWRP and the Interamerican Association for Environmental Defense have done some work to characterize subsurface ground water.

Dr. Sayler asked where the majority of the DWRP work is conducted. Ms. Gutierrez replied that several divisions are involved in the program. Much of the work is performed in Cincinnati, Ohio, including work on methods and treatment/risk management. Health effects research is conducted at Research Triangle Park (RTP), North Carolina, and the grants program is administered in Washington, DC. Ms. Gutierrez added that Dr. Sayles would cover this in his presentation.

Dr. Sayler asked about evaluating leadership. Ms. Gutierrez described leadership as recognizing when an issue is "bigger than we are" and convening a group of people to address it. Leadership also involves the ability to develop research plans that go beyond what the Agency might do by itself, not simply thinking in an ORD-centric way. Scientific leadership also is quantifiable by published research (i.e., new information contributed to major journals). The issue of outcomes has challenged the program to document this; the PART process has pushed ORD to communicate those metrics.

A participant asked for an example of convening research by setting an agenda beyond what is ORD-centric. Ms. Gutierrez replied that the DWRP undertook a set of research priorities in the area of risk management of perchlorate in drinking water. These activities are in progress.

Dr. Hauchman added that after the SDWA was passed, there were some increased requirements for health effects evaluations. The DWRP initiated an interagency meeting with the National Institute of Environmental Health Sciences, the National Toxicology Program (NTP) in particular, to conduct toxicology evaluations. In the next few years, there were several more collaborations with NTP scientists and the Centers for Disease Control and Prevention (CDC).

Dr. Sayler asked how information is communicated to the public when public health concerns arise. Ms. Gutierrez explained that program staff do not communicate continuously with the public. In the event of a public health concern, the DWRP would work closely with OW, which likely would be the direct communication channel to the public. The DWRP uses Web sites and other methods to communicate its research, and much of its work is available to the public. The program has produced several publications targeted toward the public (e.g., individual well owners).

OVERVIEW OF THE DRINKING WATER RESEARCH PROGRAM
Dr. Greg Sayles, Acting National Program Director, DWRP, NRMRL, ORD, EPA

Dr. Sayles welcomed the participants and thanked the Subcommittee members for their work in evaluating the DWRP. He explained that his presentation of the program's design and relevance

would be followed by Dr. Goodrich's discussion of LTG 1 and Dr. Hauchman's discussion of LTG 2. There will be a poster session followed by a discussion period after each of the LTG presentations. The first poster session, focused on LTG 1, addresses arsenic and surface water/ground water pathogens. The afternoon poster session, focused on LTG 2, addresses DBPs and distribution systems. The next day will include a poster session for LTG 2 and presentations on the relevance of the DWRP. Dr. Sayles said he has been leading the program for the past 2 or 3 months. Until the end of last year, Dr. Hauchman, who will be presenting LTG 2, led the program.

Why Do We Have a Drinking Water Research Program?

Goal 2 of EPA's Strategic Plan is to ensure safe and clean water. The DWRP supports that goal by conducting research. The objectives of this goal are to: (1) protect human health by reducing exposure to contaminants in drinking water and protecting source water; and (2) use science and conduct research to inform decisions that lead to the protection of human health and drinking water.

The SDWA, now 30 years old, was signed in 1974 and amended in 1986 and 1996. The 1996 amendments set up budget provisions and two specific areas that impact the research. The first is the 6-year review of regulated contaminants. EPA is required to use available science to review regulated contaminants, and ORD is called on to update that science. The second area is unregulated contaminants, the Contaminant Candidate List (CCL) process. This is a multi-step process; OW makes determinations based on many levels of science contributed by ORD's DWRP.

The SDWA also includes specific research provisions because the 1996 amendments require regulations to be based on sound and objective science. These provisions include research in the following areas:

- ✧ Microbial pathogens and disinfectants and DBPs rules
- ✧ Health effects of *Cryptosporidium*, DBPs, and arsenic
- ✧ Subpopulations at greater risk
- ✧ Biological mechanisms
- ✧ Waterborne disease occurrence
- ✧ Sulfate and radon
- ✧ Research to support the CCL.

How Does OW Use DWRP Products?

The DWRP supports the mission of safe drinking water, which is carried out by OW. The CCL process and the 6-year review are tied together. The CCL process begins by listing chemicals and considering some for regulatory determination. Certain contaminants are designated to be regulated; an implementation period follows the regulation. Six years after a contaminant is regulated, it must be reconsidered.

The components of the DWRP help inform the major decisions. These components include health effects work, methods and exposure, risk assessment, and risk management. The CCL listing process and the development of occurrence data involve the health effects work, especially hazard identification, and the development of chemical and pathogen methods. Part of the CCL process involves the development of occurrence data. The Unregulated Contaminant Monitoring Rule (UCMR) allows the DWRP to collect monitoring data, and the research program develops some of the methods to support that effort.

One of the first steps in regulatory determination is to develop a risk assessment to help establish health goal numbers, and many programs contribute to this step. The DWRP performs some risk assessments and develops methodologies for new risk assessments. Regulatory determination also involves identifying the level at which a contaminant can be monitored; ORD has developed methods for that process.

The Agency must make decisions regarding the cost and effectiveness of treating contaminants. Risk management involves treatability and residuals management, which eventually contribute to generating the CCL. ORD supports the implementation phase of the CCL. For example, as a regulation is implemented in the field, ORD might continue to improve the monitoring methods. Guidance also could be developed for implementing treatability options. Finally, the Agency must decide whether to continue regulating specific contaminants. OW asks ORD to develop new science to help make those decisions. For example, in the area of health effects, better treatment methods, such as low-dose effects or monitoring at a lower level, might be developed.

Dr. Sayles emphasized that the Agency has been conducting drinking water research for a long time, and the need for this research will continue. In the past 4 to 6 years, new areas have come to the forefront and challenged the research program, including homeland security, arsenic, *Cyanobacteria*, nanoparticles, emerging contaminants (e.g., endocrine disrupting chemicals [EDCs], personal care products), source water protection, perchlorate, and newly discovered DBPs.

How Do We Decide What To Work On?

Dr. Sayles explained that all of the DWRP's work must contribute to the strategic goal of supporting decisions that ensure safe drinking water. This is accomplished by working with the program's clients. The primary client is OW; secondary clients include the states, municipalities, and utilities. The DWRP works with OW to understand its research needs. There are a number of research plans and other documents that help guide the research, including the Arsenic Research Plan, the Microbial and Disinfection Byproduct (M/DBP) Plan, and a series of National Research Council (NRC) documents. Research scoping workshops focus on the current status of DBPs and work on *Cyanobacteria*. Academics from the research community help develop research needs documents and participate in workshops to inform the research program planning. The MYP articulates the research direction and schedule, extending 5 to 7 years in the future. Each laboratory and center develops an approach for implementing the MYP. The annual prioritization process determines the specific direction of the research.

The current emphasis is on arsenic, lead and copper, DBPs, and CCL pathogens and chemicals. Emerging areas include proteomic/genomic approaches, distribution systems, water reuse, susceptible populations, and source water protection. Several posters discuss these topics. The drinking water STAR grants are based on client (particularly OW) needs, and help fill gaps in the Agency's capabilities. Consideration is given to whether research can be accomplished internally or must go to the external expert research community. Recent requests for grant applications include Method Development for CCL Microorganisms (1991); Pathogen Infectivity and Treatment and Pharmaceutical and Personal Care Products (2000); Health Effects of CCL Chemicals and Microbial Risk (2001); Microbial Risk (2003); and Quantitative Assessment of Pathogens (planned for 2005).

Dr. Johnson asked about the MYP and the funding decisions for different programs. Dr. Sayles explained that the NPD and the research coordination team (i.e., representatives from each laboratory and center and OW) make yearly decisions about prioritizing work and allocating it to the laboratories and centers. Implementation plans also are developed for several years and assume flat funding; these plans need to be revised if funding and other priorities change.

Dr. Johnson asked whether more funding would go to the STAR Program if the highest research priorities could not be addressed within ORD. Dr. Sayles replied that it would have to be discussed with the NPD and ORD management. ORD has the flexibility to move the funding between laboratories and centers and to increase the budget for the STAR Program.

What Is the Relationship to Other Organizations?

The DWRP interacts with other Agency programs as well as organizations external to EPA. The ORD programs with which the DWRP interacts include the Human Health Research Program, Water Quality Research Program, Computational Toxicology, and Homeland Security. Some of the products are co-listed and co-funded in other MYPs.

The DWRP collaborates with the following external research organizations: the Water Environment Research Foundation, AwwaRF, WateReuse Foundation, and the Global Water Research Coalition, which includes countries such as Australia, Germany, the United Kingdom, South Africa, the Netherlands, and France. ORD also participates on the research advisory board of the WateReuse Foundation.

How Do We Demonstrate the Program's Performance?

The DWRP design flowchart illustrates resources coming into the program and eventually resulting in environmental outcomes (i.e., protecting human health and drinking water). To protect drinking water, contaminants must be reduced. Consequently, regions, states, and local water authorities must implement regulations that minimize contaminants from source water and distribution systems.

ORD develops new scientific knowledge, data, and approaches, which OW uses to make decisions required by the SDWA for regulated (LTG 1) and unregulated (LTG 2) contaminants. ORD's products, therefore, inform OW's decisionmaking. They are produced through

intramural and STAR research, and by allocating the necessary resources (i.e., personnel and funds). Ultimately, the outcomes contribute to the Agency's mission. ORD is held accountable for outcomes, not just outputs as in the past. Because ORD is accountable for clients' use of its products, the planning must involve the clients to ensure that resources are allocated and products are timed appropriately. ORD reformulated the LTGs to be more outcome oriented. An independent expert review panel will assess progress on the LTGs.

Dr. David Sedlak asked whether this process pushes the program in a certain direction. Dr. Sayles explained that the program has to consider documenting its products' use in a transparent and inclusive way. OW cites the work in its regulatory documents. As a result, that work is used in its basic publication form. The program must work with OW to identify the most usable product formats, which might be synthesis documents.

LTG 2 states that OW will use ORD's relevant, timely, and leading-edge data, tools, and technologies in decisions leading to a scientifically sound CCL. An independent expert panel will evaluate the progress toward this goal after the key regulatory dates of 2008 and 2014.

The drinking water MYP was published in 2003 and updated slightly in 2004. It describes the strategic directions and priorities of the DWRP through 2010. The MYP was developed in collaboration with the DWRP's primary client, OW. It describes research directions and specific LTGs, annual performance goals (APGs), and annual performance measures (APMs). The APMs are specific research products that the clients expect. The Science Advisory Board (SAB) reviewed the MYP in 2004; the next update will be in 2005-2006.

The 2003 MYP was output oriented and divided into regulated and unregulated contaminants. The new LTGs are outcome oriented, and the focus areas will be developed further this fall, when the MYP is revised. LTG 1 involves arsenic, DBPs, surface water/ground water pathogens, the 6-year review, and distribution systems. LTG 2 involves CCL pathogens and chemicals, innovative methods, and source water protection.

Extensive peer review is used to ensure accountability. The SAB and the BOSC review the research plans. The SAB also conducts an annual budget review. The review being conducted by this BOSC Subcommittee covers the entire program. Individual laboratories with drinking water programs are peer reviewed by *ad hoc* panels.

DWRP publications are numerous and influential—1,239 peer-reviewed publications (i.e., articles and EPA reports) and 827 peer-reviewed journal articles were published between 1995 and 2005. More than one fourth of these products were defined as "highly cited" and one third were published in "very high impact" journals, according to industry benchmarks.

The DWRP is multidisciplinary and relies on many organizational units across ORD. Health effects and exposure research is conducted at a new laboratory in RTP. The Andrew W. Breidenbach Environmental Research Center houses the methods development work and risk management research related to treatment/distribution systems. The headquarters office (ORD management, budget, and regulatory support) is located in Washington, DC. EPA's Human Studies Facility in Chapel Hill, North Carolina, conducts human exposure and air exposure

studies. The Pipeline Field Demonstration Facility in Edison, New Jersey, will be used to conduct risk management as it relates to infrastructure and homeland security. The program's greatest resource is its diverse group of scientists, including: chemists, toxicologists, environmental engineers, biologists, microbiologists, epidemiologists, statisticians, and hydrologists. The DWRP benefits from this synergy.

The DWRP has had flat funding for the past 5 to 6 years. Congress has added approximately $4 million over the past 2 years. Currently, about 150 full-time employees provide in-house research. The DWRP research is communicated via publications, the ORD Science Inventory, the Drinking Water Research Information Network (DRINK) database, scientist-to-scientist meetings (e.g., EPA workshops, and international and national symposia), Web sites, and technical assistance to clients.

Questions and Answers

Dr. Ward asked if having separate, distant geographic locations affects the selection of scientists for research projects or their interaction. Dr. Sayles explained that ORD has a staffing plan for the future that anticipates research needs. The laboratories and centers have scientists who have a wide diversity of skills. When a particular research need arises and a team is required, the appropriate staff will be pulled in.

Dr. Raymer asked whether an internal program exists to verify, promote, or assess the way in which outputs are used. It is clear that outcomes are somewhat beyond the program's control. Dr. Sayles replied that ORD is developing an information-gathering infrastructure to gather the information needed to assess how ORD's outputs are used. This system should be developed in the next several months.

OVERVIEW OF LTG 1 RESEARCH
Dr. James Goodrich, Acting Director, Water Supply and Water Resources Division, NRMRL, ORD, EPA

Dr. Goodrich stated that his presentation would address the DWRP's regulated contaminants research component and its integration with OW's timeline and approach.

The regulations concerning LTG 1, regulated contaminants, have been in place for 20 to 30 years and longer. The DWRP features cutting-edge research and focuses on specific contaminants, new methods for risk assessment and health effects, monitoring, and distribution systems. Distribution systems, which account for 80 percent of a typical household water bill, are a unique ecosystem—the kinetics, the biology, the chemistry, and the physical integrity. What happens to contaminants when they reach distribution systems from treatment plants is a new area of emphasis.

The DWRP also features synthesis products, including documents on arsenic treatment technology, health effects, DBP reproductive effects, and distribution system management. These areas represent the past, present, and future. Currently, DBPs are an example of cross-ORD interaction. ORD's research priorities include arsenic, DBPs, *Cryptosporidium*, lead, and

copper. Goals related to these areas will become final late this year or early next year. Additional research priorities include crosscutting and emerging issues such as distribution systems; innovative approaches for contaminant characterization, prioritization, and treatment; health effects in sensitive subpopulations; and small drinking water systems. Small drinking water systems comprise 80 percent of the systems in the United States; these are where most of the violations of the MCL occur.

The key research questions for LTG 1 include:

- ✧ What is the most effective and least expensive arsenic treatment technology?
- ✧ How do low doses of arsenic affect health?
- ✧ What are the DBP reproductive effects? How can DBPs be managed more effectively? How can treatment and distribution systems be managed more effectively to mitigate DBPs at the tap?
- ✧ What new detection, treatment, and assessment technologies are available to control *Cryptosporidium*, bacteria, and viruses while balancing DBP formation?
- ✧ How can water quality in distribution systems be characterized and maintained more effectively (i.e., maintain good water quality to the tap)?

Arsenic

The DWRP's regulatory approach for arsenic comprises the Arsenic Rule, the DBP Rule, Surface Water Rule, Ground Water Rule (GWR), and the 6-year review. All of these rules will come to a head in the next few months. APGs and APMs in the program are leading up to decisions. The Arsenic Rule is subject to the 6-year review process. In 1976, EPA set the MCL for arsenic at 50 µg/L; in 2001, it set a new MCL of 10 µg/L. The MYP includes specific questions: What are the most cost-effective technologies to remove arsenic from drinking water and manage residual wastes that might be produced? How can the information about the relationships between low-dose exposures to arsenic and health effects be improved?

In ORD's risk paradigm, health effects data, risk assessments, and treatment technologies all contribute to OW's decisionmaking. Specific work groups provided data that informed the 10 µg/L figure. January 2006 is the deadline for compliance with this new level. Treatment technology demonstrations and health effects research has continued and, in 2007, the Arsenic Rule will be subject to the 6-year review again. The pipes themselves may be a source of arsenic. OW will determine what happens to the MCL level (i.e., whether it increases, decreases, or remains the same).

The research impacts of the Arsenic Rule include improved risk estimates for low exposure doses and cost-effective treatment technologies. ORD has developed guidance documents and manuals for arsenic removal, and 40 demonstrations of treatment technologies are ongoing, in

addition to the technologies being verified under the Environmental Technology Verification (ETV) Program. This meeting includes six posters related to arsenic.

Surface Water/Ground Water Rules

The implementation focus for the Surface Water/Ground Water Rules includes the Interim Enhanced Surface Water Rule, the Stage 1 DBP Rule, Long-Term 1 Enhanced Surface Water Treatment Rule (LT1ESWTR), and the Filter Backwash Rule. All of these are in place and leading up to the Long-Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR). LT2ESWTR applies to all surface water systems and includes risk-based monitoring to identify systems with the highest vulnerability to *Cryptosporidium*.

The key scientific questions for the Surface Water/Ground Water Rule include:

- ✧ How can *Cryptosporidium* be sampled and detected?
- ✧ How can risk assessments of virus and protozoa in surface water and ground water be improved?
- ✧ How can treatment be optimized to remove and/or inactivate *Cryptosporidium*?
- ✧ How can *Cryptosporidium* be controlled at the treatment plant? (Chlorine is not very effective.)

Surface water/ground water research involves: (1) improved methods to identify *Cryptosporidium* oocysts and determine infectivity and virulence; (2) assessment of the utilities' vulnerability; and (3) improved treatment methods for pathogens.

Research impacts of LT1ESWTR and LT2ESWTR include epidemiology studies that support enhanced surface water treatment rules. STAR grant research has provided data on *Cryptosporidium* infectivity. These new data permitted the calculation of health risk reduction benefits for the proposed LT2ESWTR. Disinfection credits of *Cryptosporidium* by UV light, ozone, and chlorine dioxide were developed for the LT2ESWTR. Guidance documents also were developed on the use of bag filtration and cartridge filters to achieve 2 log reduction of *Cryptosporidium* for small drinking water systems for the LT2ESWTR.

Ground Water Rule

The GWR provides states with more flexibility. In support of this rule, ORD developed, and is continuing to evaluate, bacterial and viral detection methods; conducted a national ground water study to provide an economic assessment of the GWR; and developed statistical models for assessing variability in exposure to *Cryptosporidium* for use in the GWR and LT2ESWTR.

Dr. Goodrich added that the poster session for surface water and ground water features a combination of in-house and extramural work and covers topics such as protozoa detection methods for *Cryptosporidium*, *Microsporidia*, and *Cyclospora,* and ETV field evaluations.

Disinfectants and DBP Rule

The Stage 2 DBP Rule (DBPR) applies to all community water systems and non-transient, non-community systems that add a primary or residual disinfectant (except for UV light) or deliver water treated with a primary or residual disinfectant. A key scientific question for this rule is how to improve characterization of the health effects of high-priority byproducts and DBP mixtures. DBPs do not occur one at a time. There is a "whole soup" of these; some are increasing, some are decreasing. Some byproducts to consider include chlorine becoming chloramines and ozone converting to oxides.

There are several impacts of the DBP Rules. The World Health Organization (WHO) often looks to ORD's MCLs for its starting points. ORD's research supporting nonlinear carcinogenic mechanisms for chloroform was cited as the basis for changing the chloroform maximum contaminant level goal (MCLG) to 70 ppb in the proposed Stage 2 DBPR. In addition, the potential cancer and noncancer risks associated with DBPs supported the decrease of EPA's Total Trihalomethane Standard Stage 1 DBP Rule. EPA Method 415.3, Total Organic Carbon and Specific UV Absorbance, was developed to support monitoring and DBP precursor removal decisions.

The DBP poster session covered topics such as pregnancy loss and drinking water, developmental effects, complex mixtures, trihalomethanes, reproductive and neurological outcomes, chlorinated and brominated haloacetic acids (HAAs), and dichloroacetic acid-induced carcinogenesis.

Six-Year Review of Existing Regulations

Cycle 1 of the 6-year review of existing regulations began in 1996 with the SDWA amendment, and all of the rules up to that point will be on that cycle. ORD will complete the second 6-year review cycle in 2008. When a new rule is passed, the 6-year clock begins ticking on it. Throughout the timeline, there are several concurrent 6-year reviews. The drinking water MYP includes work on risk assessment, health effects, updating current information, new technologies, and analytical methods (e.g., for measuring perchlorate).

Under the 6-year review, the Lead and Copper Rule goal is to optimize treatment, remove lead service lines, and identify contributions from source water and pipes.

Issues for the Total Coliform Rule (TCR) include monitoring, microbial indicators, and site sampling plans. Greater flexibility is needed for monitoring at critical and vulnerable sites. Distribution systems will involve characterization of contaminants and types of failures (e.g., when remediation of microbes creates DBPs). Simultaneous compliance with multiple regulations is a significant challenge for water utilities.

The poster session for distribution systems included such issues as lead and copper contamination, corrosion and release of contaminants, biofilms, and infrastructure security. The

distribution systems are the most vulnerable points in terms of homeland security. Much of this research is coordinated through the Office of Homeland Security.
In summary, near-term regulations that are under development include the GWR, LT2, DBP2, and the Lead and Copper Rule. The 6-year review of the Arsenic Rule is scheduled for 2007-2008. The TCR and Distribution System Rule will be issued in 2008.

Questions and Answers

Dr. Sedlak asked about the types of research needed to address future issues such as susceptible populations. Dr. Goodrich replied that the DBP issue increases when wastewater disinfection begins. DBP-related issues will become prominent (e.g., whether DBPs should become part of the CCL). This also involves issues of ecosystem restoration.

Dr. Johnson commented that with the 6-year review and other regulations, the workload seems to be increasing, which likely would decrease resources available for research. Dr. Goodrich added that the CCL contains 50 contaminants that were designated to be regulated. Optimizing existing regulations versus determining new threats is an important issue.

Dr. Sayler asked whether a cost-benefit analysis could be done (e.g., *Cryptosporidium* versus DBPs) so that these issues could be addressed strategically. Dr. Goodrich explained that discussions with OW determine the regulatory impacts, such as the number of utilities that are affected. ORD addresses the issue as it revises the MYP, and OW reviews it.

Dr. Raymer asked about increased rates of failure. The infrastructure gap is huge; the replacement rate of water utilities is 200 years. How can the risk level be determined from a pipe that is cracked or leaking? Dr. Ward noted that there should be a mechanism for utilities to communicate with EPA in the event of such a problem so that surveillance can be done.

Dr. Sedlak asked how the research is prioritized. The arsenic research, for example, could have a large economic impact. Is the research prioritized by economic impacts, gaps in the research, or by projects that EPA could do that are unique and not being done elsewhere? Dr. Goodrich answered that the MYP addresses the research priorities for individual laboratories.

LTG 1 POSTER SESSION 1: ARSENIC AND SURFACE WATER/GROUND WATER PATHOGENS POSTER DISCUSSION
Drinking Water Research Subcommittee

Dr. Sayler asked if there were any questions for the Subcommittee or the poster presenters.
Dr. Johnson asked how the projects are budgeted and funded. Dr. Sayles explained that there is a planning process to determine the program's direction and identify major products. This occurs every 2 or 3 years. The DWRP works with its the clients to determine their needs and conducts workshops to determine research questions specific to the MYP. The program then commits to projects that can be accomplished in 6 to 7 years. An annual budget is established, and the research is prioritized, so if the funding is cut, appropriate decisions can be made.

Dr. Selene Chou asked about the first three posters, which relate to arsenic. What are the recommendations for managing residual wastes? How do you manage the waste that you generate? Dr. Thomas Sorg explained that the program characterizes the waste and considers waste disposal. Certain general federal regulations govern residual disposal, but in many cases, state regulations control disposal of these residuals. For small systems, some states allow backwash water into streams. Basically, waste management depends on what states allow. If there are absorption media, a Toxic Characteristic Leaching Procedure will be performed to determine whether these materials can go in the landfills. Several documents describe ways of treating the residuals; one such document provides guidance on the federal regulations plus samples of state regulations.

Dr. Chou asked about western states, which have higher arsenic levels, and small drinking water systems. Dr. Sorg replied that the issue of arsenic residuals in landfills had been raised recently. The ideal pH for absorption is 5.5 or 6. California has its own regulation. He added that "what happens in the landfill now is another question."

Dr. Sayler asked to what extent ORD issues cooperative agreements. Dr. Hauchman explained that procedures exist for in-house scientific staff to engage in cooperative research arrangements; these agreements are subjected to the same types of peer-review requirements that the Agency uses for other types of research. Many years ago, the peer-review aspect was not emphasized. Now, we are able to work with universities and other collaborators.

Dr. Sedlak asked how the cooperative agreement funding compares to the size of the STAR Program. He also asked about the peer-review process (i.e., how proposals are solicited and who does the evaluations). Have the outputs from the cooperative agreements been compared with the outputs from the internal research and the extramural research (i.e., the STAR Program)? Dr. Hauchman explained that the proposals are evaluated by a panel of external peer reviewers and then subjected to a relevancy review by EPA.

Dr. Sedlak noted that information about outcomes from the STAR Program and the intramural research is available, but he did not have information on outcomes from the cooperative agreements. Dr. Hauchman replied that collaborators are identified, and the information is available through the Science Inventory, the DRINK database, and other locations that describe the research projects.

Dr. Sayler asked about selecting the arsenic treatment technologies for demonstration. The technologies are commercially available; did EPA have any involvement in their development? Dr. Sorg explained that proposals were solicited from engineering firms and vendors after the sites had been selected. Several companies submitted proposals; one or two of them came out of the Small Business Innovation Research Program. EPA received one to eight proposals per site. A peer-review panel eliminated any proposals on technologies that were not ready for full-scale operation. EPA, the state, and the water utility collaborated on the decision. It was agreed that there would not be identical projects in the same state.

Dr. Sayler asked about the number of technologies currently being demonstrated. Dr. Sorg replied that there are absorption, coagulation, and ion exchange technologies. For absorption

technologies, he estimated that there are nine different absorption media; 60 percent of the proposals focused on some type of absorption media. There were two rounds of external peer reviews based on funding. For the first round, 80 proposals had 25 peer reviewers, and 140 proposals had 30 peer reviewers.

LTG 2 POSTER SESSION 2: DBPS AND DISTRIBUTION SYSTEMS
POSTER DISCUSSION
Drinking Water Research Subcommittee

Dr. Sayler thanked the presenters for answering questions about the posters. Dr. Ward asked if there was an assessment of the general population's exposure to DBPs, possibly through cooperative work with the National Health and Nutrition Examination Survey (NHANES). Dr. Calderon replied that NHANES has started looking at chloroform, so the next environmental report card will include some kind of estimate.

Dr. Sedlak asked how EPA's Test and Evaluation Facility (T&E) fits into the budget, planning, and infrastructure of the water research. How is research conducted through that contract, and how does it fit into the LTGs and the planning process? Dr. Goodrich responded that T&E is an EPA facility operated by a contractor. The contracts are competed and they have a period of performance of 5 years. The T&E is an extension of EPA's in-house capabilities; as NRMRL conducts research, work assignments are generated and tasked to contractors. The program maintains close interaction with the principal investigators. ORD identifies a task, and the contractors fulfill that task. The individual researcher can decide to use the T&E, do the work in-house, or complete a cooperative agreement.

Ms. Gutierrez added that the T&E is not exclusive to drinking water research. Homeland security and waste-related research also are conducted there, and the facility has the capacity to accommodate third-party contractors.

Dr. Johnson asked about LTG 1 posters 31 and 26, which discuss copper and lead contamination. The output was listed as providing information for guidance documents. In what format was the information provided, and how was this facilitated? Dr. Michael Schock replied that OW determines the format (e.g., work groups, publications, reports, or data). Dr. Johnson asked whether there were typical pathways for this information or if it was simply there for use as needed. Dr. Schock explained that OW has an agenda, and it wants particular guidance documents prepared at certain times; OW has some idea of the information that should be included. Dr. Sayles added that OW looks at ORD's projects when it is approaching a key decision. ORD and OW also meet to discuss the work in depth.

Dr. Johnson asked how ORD ensures outcomes, particularly if outputs are not related to outcomes. Dr. Tom Speth answered that ORD often has a representative on OW's work group who keeps the program informed, so we are aware of what is needed and when.

Dr. Sedlak asked about clients other than OW, and if ORD goes directly to the regions or utilities. Should the Subcommittee look for evidence of outcomes further down the chain? Are there more examples of helping the utilities directly, as was done with the Washington, DC,

distribution systems. Dr. Sayles explained that the research program was established to help EPA ensure safe drinking water, so EPA has to be the primary client. Other entities, such as states and utilities, must respond to EPA. The DWRP supports the implementation phase.

Dr. Sedlak asked if resource limitations resulted in tradeoffs that made the program unable to meet secondary clients' needs. Dr. Goodrich replied that clients seeking new technologies for meter reading, for example, would be directed to the American Water Works Association (AWWA).

Dr. Ward commented that epidemiology studies are expensive, and many are conducted outside of EPA. She asked about funding and how EPA cooperates in these studies. Dr. Calderon answered that it depends on the area of drinking water. Many microbial studies and arsenic studies were funded in-house. For DBPs, two approaches were taken. Resources were leveraged with other federal agencies, particularly the CDC. For birth defects research, EPA can add these efforts to the Agency's birth defects centers. A Request for Proposals was issued for the spontaneous abortion study.

Wednesday, June 22, 2005

INTRODUCTION

Dr. Gary Sayler, Chair, Drinking Water Research Subcommittee

Dr. Sayler reviewed the events from Day 1 of the meeting. The primary focus was LTG 1, "OW uses new scientific data and approaches developed by ORD to make decisions on regulated contaminants." The Subcommittee examined the specific research through the poster session, which provided an overview of the technical merits as well as the process by which research outputs lead to outcomes.

Dr. Sayler stated that Day 2 of the meeting would focus on LTG 2. The afternoon session would include OW, state, and local perspectives. Mr. Kim Fox will present the Homeland Security perspective instead of Mr. Jonathan Herrmann. There will be time for public comment and for the Subcommittee to work on the writing assignments.

OVERVIEW OF LTG 2 RESEARCH

Dr. Fred Hauchman, Acting Director, Microbial and Chemical Exposure Assessment Research Division, National Exposure Research Laboratory (NERL), ORD, EPA

Dr. Hauchman began by addressing several issues raised during Day 1: (1) How does EPA identify and prioritize research? (2) Who are the clients and partners, and how are they selected? (3) How do the clients use the products and what are the impacts? (4) How are results communicated? and (5) What is EPA's leadership role? Dr. Hauchman reiterated that the DWRP's primary mission is to support EPA's strategic goal of ensuring safe drinking water. The blueprint is the SDWA, particularly the 1996 amendments, which have provisions for the kinds of work, timelines, and recommendations for public and stakeholder involvement.

To answer the five questions listed above, Dr. Hauchman used DBP research as an example. EPA has played a leadership role in this research since the early 1970s, when the first DBPs were identified. EPA was responsible for generating the scientific database that led to the Trihalomethane Rule and its subsequent iterations. Research was conducted in all areas of the risk paradigm: exposure, occurrence, development of detection methods, treatment technologies for removing and reducing DBPs, and health effects studies, both toxicological and epidemiological. As many DBP issues have been addressed and new issues have emerged, the emphasis on DBPs has decreased. Currently, the focus is on the remaining highest priority needs: potential adverse reproductive outcomes and complex mixtures.

Three interrelated approaches were used to determine the DBP research priorities: a risk-based approach to identify needs; extensive interactions with clients, stakeholders, and the scientific community; and an internal assessment of EPA capabilities and capacities.

To address the research needs, EPA initiated a large collaborative research effort. The health effects program within EPA had extensive capabilities in the area of toxicology, and was appropriate for studying adverse reproductive issues. EPA also has a strong epidemiology program. An aggressive research program was launched, focused on adverse reproductive issues, which was the area of greatest need. By collaborating with the Microbial Disinfection Byproduct Council and other government organizations, EPA was able to co-fund several major efforts, including a multimillion-dollar reproductive epidemiology study. EPA engaged the NTP to conduct screening studies and worked with CDC in the area of epidemiology.

To communicate the results of the research, reports and publications were developed and delivered to OW after peer review. Status briefings with EPA were conducted while the research was in progress and after they had been peer reviewed. The research also was presented at scientific and stakeholder meetings, including Federal Advisory Committee Act (FACA) negotiations. The results of the research provided critical information used in the development of the Stage 2 DBP rule requirements that address adverse reproductive outcomes.

Dr. Hauchman described a similar approach for *Cryptosporidium* research. The SDWA amendments recognized the need to strengthen requirements for protecting public exposure to waterborne pathogens, particularly *Cryptosporidium*. A series of rules was developed and implemented concurrently with the DBP rules.

Several needs were identified, including improved recovery and detection methods, better information on health effects, and information on treatment methods to inactivate or remove *Cryptosporidium*. As with the DBP program, the research needs were prioritized using a risk-based assessment of needs; extensive interaction with clients, stakeholders, state and local authorities, and the scientific community; and an internal assessment of capabilities and capacities.

The research needs were addressed through an integrated response. NERL scientists and outside collaborators conducted an in-house research effort on detection and recovery. NERL, NRMRL, the National Center for Environmental Research (NCER), and the National Center for

Environmental Assessment (NCEA) each provided specific research, and there were close interactions with industry.

Dr. Johnson asked about in-house research. Was the work assigned via proposals or simply by tasks, and was the internal work peer reviewed? Dr. Hauchman responded that each laboratory and center uses a slightly different process. NERL's review process involves a formal proposal and peer review. There might be an outside review as well.

To communicate the research results, ORD delivered reports and publications to OW after an outside peer review, provided status briefings within EPA on high-impact studies while the research was in progress and after the peer review, and gave presentations at scientific and stakeholder meetings.

Dr. Johnson asked whether OW has indicated that the information format is useful to them, and Dr. Hauchman affirmed that it has. For example, NERL assesses each deliverable through a strategic customer-value analysis, which includes the product, customer response, and how the product was used. The *Cryptosporidium* research results provided critical information used in developing the Surface Water Treatment Rules. The infectivity studies provided important information on assessing the risk associated with *Cryptosporidium* exposure, and the treatment studies helped water utilities meet the requirements of the rule.

To assess the leadership of EPA's DWRP, Dr. Hauchman suggested the following criteria:

- ✧ Building consensus about science and research needed to achieve the nation's strategic goal for drinking water.
- ✧ Engaging partners and stakeholders to address these needs.
- ✧ Conducting internationally recognized, leading-edge research to advance the science.
- ✧ Communicating effectively.

Dr. Sayler asked how to determine whether the program is recognized nationally and internationally. Dr. Hauchman suggested counting the number of times EPA researchers are invited to national and international meetings and by evaluating the presentations. He also relayed his experience with the Global Water Research Coalition, a world-wide consortium of leading water research organizations. EPA's participation is considered a major coup for the coalition, and it helps representatives from other countries gain support from their boards to participate.

Dr. Hauchman added that, from his perspective, the program is now in transition. Many of the needs for the regulated contaminants have been addressed. The program has a good track record for DBPs, arsenic, and other contaminants, and now is moving into emerging issues. Full-scale CCL research has been active for only 4 years, and publications reach a level of high standing over time. With resources decreasing, the program will rely on leveraging resources with other

organizations, including other federal agencies, the STAR Program, and internal programs, such as the Computational Toxicology Program.

Dr. Sedlak asked for examples of international recognition for the program's leadership role. Dr. Hauchman replied that EPA scientists have been at the forefront in developing WHO guidance documents. EPA has contributed much of the technology-related research to address issues concerning arsenic levels. For DBP research, Dr. Hauchman noted EPA's participation in the Organisation for Economic Co-operation and Development.

Dr. Ward commented that LTG 1 requires conducting a review. Research in regulated contaminants is decreasing, but the SDWA amendments require a regular review. She asked about plans for exposure studies, whether exposure has changed with the new regulations, and whether there would be outcomes or epidemiologic followup studies. Dr. Hauchman explained that OW developed an elaborate process with respect to the 6-year review. This was a FACA effort to develop procedures for reviewing each of the regulated contaminants and standards and evaluating the data gaps. OW, using input from the FACA process, will continue its risk-based process to assess gaps in research. There will not be an emphasis on epidemiological studies for regulated contaminants that are not considered to be high priority, except perhaps in special instances.

LTG 2

The theme for LTG 2 is research supporting Agency decisions on the CCL. The new LTG 2 states that OW and other key clients use ORD's relevant, timely, and leading-edge data, tools, and technologies in decisions leading to a scientifically sound CCL process. Progress toward this goal will be determined by an independent expert panel after the key regulatory dates of 2008 and 2011.

LTG 2 includes both CCL-related research and source water protection research. CCL regulatory determinations are made in 5-year cycles. According to a 2001 National Research Council report, EPA needs to develop new innovative methods for prioritizing contaminants, reducing the number of potential substances of concern, and reducing the number of contaminants to a more manageable list. The UCMR includes several specific requirements for utilities. In addition, the SDWA requires or promotes specific actions to protect source waters, including assessment, monitoring, and treatment.

Decisions on CCL contaminants involve three steps: regulatory determination, implementation, and the 6-year review. The APGs in the MYP were designed to inform decisions. This was a purposeful attempt to ensure that the research would be available in time for critical milestones (i.e., the 2008 and 2011 deadlines). Currently, the CCL lists 9 pathogens and approximately 50 chemicals, including inorganics and organometals (e.g., aluminum and organotins) and organics (e.g., pesticides, EDCs, and industrial chemicals). Each contaminant has a different suite of needs. The CCL research is divided into two major directions. The first is to conduct research on specific high-priority contaminants. This research fills in data gaps, determines which contaminants to regulate, and identifies appropriate regulations. The second research direction

involves developing innovative approaches to identify and prioritize the contaminants on the CCL and measure the risk associated with them.

Contaminant-specific research includes: (1) developing screening level and detailed health effects data for use in assessing risks; (2) developing sensitive, specific, and cost-effective analytical methods for UCMR monitoring, compliance, and research; (3) assessing human exposures and risks for pathogens and chemicals; and (4) evaluating the effectiveness of treatment technologies and determining the most cost-effective risk management approaches.

To prioritize the list of chemicals and pathogens, the program initially emphasized developing analytical methods to assess risk and evaluate the effectiveness of advanced treatment technologies.

Innovative approaches involved the development of: new models, methods, and data; new data and tools for determining cost, feasibility, and performance of technologies; and new data, tools, and approaches for conducting risk assessments.

The impacts of this research include data, methods, and approaches to support CCL decisions. Health data were assessed for CCL chemicals. Studies on propanes and propenes indicate that they might not be of concern. Analytical methods were developed for UCMR1 and will be used in UCMR2 (the second round of UCMR monitoring). All utilities participating in the UCMR are required to use these methods. An estimated 270,000 measurements will be made by 5,000 utilities using the methods ORD developed in collaboration with OW. Other impacts include improved pathogen detection methods for research and monitoring. Significant advancements are being made in this area with bacteria and viruses. In addition, risk characterizations for CCL contaminants have been completed and will be considered in decisionmaking.

Dr. Sayler commented that the UCMR work sounds very impressive and demonstrates unique leadership. Dr. Hauchman added that, considering the short timeframe, EPA is the only organization working on these methods. N-nitrosodimethylamine (NDMA) is a good example in which EPA consulted with the WateReuse Foundation, which also had a solicitation to develop an NDMA method. Their collaboration prevented a duplication of method. Dr. Hauchman stated that EPA is not the sole developer of these methods, but this is a sensitive, specific method that can be used nationally.

Regarding source water protection, the key scientific questions fall into four areas:
(1) development and improvement of water quality criteria; (2) source water assessments;
(3) prevention measures to address contamination sources; and (4) contingency planning (e.g., early warning systems). This research is linked with ORD's Water Quality Research Program and the U.S. Department of Homeland Security; this is an area in which ORD needs to prioritize the risk and determine how the program complements studies conducted in other areas of EPA. The impacts of the source water protection program include new data and methods to assist drinking water utilities and local authorities in assessing and protecting water quality.

To summarize LTG 2 research, the DWRP supports a comprehensive, risk-based prioritization approach for future decisionmaking on contaminants of potential concern; allows for

consideration of emerging and longer term research issues; and promotes the development of innovative approaches that have created new opportunities to use the latest technologies to advance the science. The next chapter of the DWRP will involve such issues as water reuse, dwindling water research, and growing populations.

LTG 2 POSTER SESSION: CCL, INNOVATIVE METHODS, AND SOURCE WATER PROTECTION POSTER DISCUSSION
Drinking Water Research Subcommittee

Dr. Raymer commented that he saw a lot of interesting work on analytical methods development, but asked about launching into a development effort. Is there any indication of how low to push the limits? Are they based on toxic or dosing information, and how does one determine that the methods developed are going to be used adequately for screening? For example, according to the EDCs poster, the limits of detection were limited in part by the instrumentation. At the limits of detection, there were still profound effects observed in the fish in terms of endocrine disruption. He added that the detection limits should be low enough to measure below the point at which biological effects are observed.

Dr. Kathleen Schenck responded that Dr. Raymer was referring to her poster. She explained that the limit of detection is limited somewhat by the fact that they only have one MS. The MNDLM assay tends to be a little low. We can see 10^{-12} molar; that is probably a little low, but not much. Regarding the treatment scenarios, the influent dose or the pretreatment dose was increased so that even if there was a high rate of removal, the post-treatment has at least a few nanograms/L. In this way, there is a true number to quantify the removal.

Dr. Sedlak asked why EPA is studying the efficacy of drinking water treatment plants to remove a contaminant of ecological concern. Several posters demonstrated studies on treatability that did not have a clear link to drinking water concerns and were driven more by public perception. It seems that by conducting research according to public perception, EPA might be legitimizing a certain response. When the CCL contaminants come up, how do the toxicologists input the engineering and treatability studies? Dr. Goodrich replied that, specifically with the EDCs, a decision was made to do this work in parallel with methods development. OW had this priority and provided the funding initially. Dr. Schenck added that public perception might have an impact, but the utilities are interested in responding to public concerns about safe drinking water. Although the stories in the press are about fish, if the source is the same as the drinking water, there is concern.

Dr. Ward asked about DBPs. With the long list of chemicals on the CCL, was there any initiative to work with CDC and its National Health Examination Survey? She explained that CDC conducts a general population survey to determine exposure to a wide variety of chemicals. Dr. Hauchman answered that there was not, although EPA looks for opportunities to work with CDC. It is a matter of leveraging funds; CDC has its own list of priorities. Dr. Ward noted that the Office of Pesticide Programs has provided additional funding for NHANES to look at specific pesticides in blood in a targeted subpopulation. There is a precedent at EPA for that kind of effort.

Dr. Goodrich mentioned the homeland security centers. A consortium of organizations is involved in source water protection, including the energy laboratories and the U.S. Army. One participant commented that, based on the nationwide occurrence study, there is an opportunity to look at uncommon trihalomethanes. Another participant noted that both CDC and the Center for Homeland Security are responding to the *Cyanobacteria* issue and are developing national research plans to identify and prioritize occurrence.

Dr. Sayler asked Dr. Hauchman if there were corollaries for leadership for LTG 2.
Dr. Hauchman replied that the principles were intended to apply to the whole program. For the CCL research, risk issues and internal capacities were considered. Analytical methods research was one of the highest priority near-term needs. He added that LTG 2 involves much more creative planning.

RELEVANCE OF ORD'S DRINKING WATER RESEARCH PROGRAM
OFFICE OF WATER PERSPECTIVES
Dr. Edward Ohanian
Director, Health and Ecological Criteria Division, Office of Science and Technology (OST), OW

Dr. Ohanian outlined his discussion topics: the DWRP's organizational background, mission, critical research needs, examples of ORD support, and future needs for sound science in regulatory decisionmaking. He emphasized that the DWRP is an important undertaking for OW.

Background

OST has a new director, Dr. Ephraim King. OST works with partners and stakeholders to develop the scientific and technical foundations for clean water. OST develops tools, methods, information, criteria, and policies to protect water quality, human health, and ecosystems.

The Clean Water Act (CWA) of 1987 requires EPA to develop and publish criteria for water quality that reflect the latest scientific knowledge to protect aquatic organisms and human health. OST goes beyond aquatic life to include the human health component. Regarding human health risk assessment, the CWA and SDWA are interdependent.

Under the SDWA, OST's mission is to publish an MCLG and promulgate a National Primary Drinking Water Regulation for specific contaminants based on the following criteria: (1) Does the contaminant adversely affect public health? (2) Is the contaminant likely or known to occur in the public water system with a frequency and at levels that pose a threat to public health? and (3) Will regulation of the contaminant present a meaningful opportunity for health risk reduction? OST provides the MCLG to the Office of Ground Water and Drinking Water (OGWDW), which converts it to the MCL.

The SDWA also requires OST to review existing regulated contaminants every 6 years, determine the need for revisions of the established MCLG/MCL, and consider sensitive subgroups that are at greater risk from exposure to contaminants in drinking water. In the area of protecting human health, OST's efforts include health goals for drinking water, risk assessment

for contaminants in drinking water, guidance on unreasonable risk to health, and developing human health criteria for surface water.

Mission Critical Research Needs

OST's mission-critical research needs related to LTG 1 include general research on: (1) the effects of drinking water contaminants on sensitive subpopulations; (2) adverse effects from DBPs; (3) epidemiologic studies; (4) reproductive and developmental effects; (5) risks posed from mixtures of chemicals and contaminants; (6) chemical-specific research on priority contaminants; (7) mode of action studies; (8) pharmacokinetic modeling; (9) risk assessment related to exposure; (10) microbial risk assessment methods; and (11) measurement techniques for pathogens and chemicals. OST has received methods development and epidemiological assistance from ORD (e.g., rapid indicators). Dr. Ohanian added that OST should consider how to measure pathogens and chemicals in drinking water before addressing toxic effects.

OST's mission-critical research needs related to LTG 2 involve chemical-specific research on CCL contaminants. This includes closing critical data gaps, providing mechanistic data, identifying surrogate approaches for estimating toxicity, differentiating between parent and degradate toxicity for pesticides, and identifying new contaminants.

ORD's Accomplishments

Dr. Ohanian served as Acting Director of NCEA for 6 months to learn how ORD could work with the program offices and vice versa. ORD laboratories provide basic research on CCL contaminants, including:

- ✧ Organotins (NHEERL)
- ✧ Dichloropropanes and dichloropropenes (NHEERL)
- ✧ Aluminum (NCER)
- ✧ Development of quantitative structure-activity relationships (QSAR) approaches (NHEERL, NCEA)
- ✧ Cumulative risks for CCL pesticides (NCEA).

ORD's accomplishments in the area of DBPs include chemical-specific studies, reproductive and developmental studies, and research on mixtures of DBPs. ORD also defined approaches to identify EDCs for inclusion on the CCL. In the area of microbial research, ORD characterized spatial, temporal, and environmental factors at marine and fresh water beaches (e.g., the Great Lakes). Four epidemiological studies are ongoing to help ORD develop recreation water criteria. ORD also established testing parameter protocols for viruses and *Cryptosporidium*.

Future Needs

Future needs will involve omics data translated to risk assessment. As a program office, ORD must communicate with risk managers when achieving verdicts. ORD must ensure that the confidence level is there for cancer and noncancer studies. The strengths and weaknesses of the studies also must be evaluated and transmitted. Other future needs include the impact of genetic

polymorphisms on susceptibility, screening studies to identify emerging contaminants, evaluation of the potency of *Cyanobacteria* toxin, and computational toxicology.

Questions and Answers

Dr. Sayler asked if ORD provided deliverables in a timely manner and in a useable format. Dr. Ohanian answered that timeliness is always a factor because of the program offices' deadlines. ORD keeps OST informed about particular research efforts before the deliverables are due, and most products are delivered on time.

RELEVANCE OF ORD'S DRINKING WATER RESEARCH PROGRAM OFFICE OF GROUND WATER AND DRINKING WATER (OGWDW) PERSPECTIVE

Mr. Phil Oshida, Acting Director, Standards and Risk Management Division, OGWDW, OW, EPA

Mr. Oshida stated that his presentation would describe the regulatory perspective and the challenges facing the OGWDW. He also would provide examples of ORD's support to OGWDW and discuss future needs.

Regulatory Perspective

The 1996 SDWA amendments changed EPA's direction and approach with respect to drinking water. The amendments require EPA to focus on primary contaminants and provide guidance for evaluating existing regulations. They established the CCL, emphasized new research, and required expanded regulatory tools (e.g., occurrence, methods, costing analysis, and economics).

Mr. Oshida stressed the importance of the quality of information. NERL provided essential data that have helped set MCLGs. Through the STAR grants, *Cryptosporidium* dose-response data were used in the economic analysis of LT2. NERL continuously provides methodologies to look for occurrence of contaminants within the UCMR program and to measure compliance for regulated contaminants.

In terms of the overall DWRP, Mr. Oshida stated that OGWDW always is excited to participate in ORD's MYP and understands its importance. It is important not only to align the strategic plan with general LTGs, but also to design it so that the information is available during the regulatory process. There are no strong lines drawn between OW and ORD; it is very much a team effort.

OGWDW uses DRINK to stay current with ongoing work in the drinking water research community. ORD provides a portal to research on drinking water and facilitates opportunities to work with other organizations.

ORD Support to OGWDW

For LTG 1, ORD has supported OGWDW for many years in the development and implementation of rules for arsenic, DBPs, Surface and Ground Water Rules, and distribution

systems. For LTG 2, OGWDW is beginning to receive the support it needs. OGWDW does not know what it might need to address the CCL or assess all of the potential contaminants. The effort to determine this is ongoing in partnership with ORD and the mission outlined by the FACA committee. For microbial and chemical contaminants, OGWDW needs innovative new methods as well as the expertise of ORD scientists to explain other existing methods. Source water protection is key; if this is achieved, the CCL could be shortened.

LTG 1

In 2002, the EPA Administrator pledged $20 million to develop arsenic-removal technologies, particularly for small drinking water systems. NRMRL completed 40 demonstration studies on arsenic removal; these have provided valuable technical assistance to many people, and guidance documents are being developed to disseminate that information further.

ORD is the worldwide leader of DBP research. ORD supported Stage 1 and Stage 2 rule development and implementation. Stage 2 will lower overall DBP concentrations in distribution systems and thereby reduce the risk to public health. NRMRL helped lower the MCL for DBPs from 100 to 80 μg/L and helped develop regulations for HAAs. NRMRL's coagulation studies supported the Stage 1 organic precursor removal requirements.

ORD has supported microbial-related rule development and implementation. Data from the *Cryptosporidium* infectivity studies allowed OGWDW to estimate benefits in LT1 and LT2. NERL provided virus occurrence data to support the GWR. NERL and NRMRL participated in several outbreak investigations that helped illustrate the need for public health protection measures under the proposed GWR. NHEERL, in collaboration with CDC, publishes a biannual waterborne disease outbreak report that helps with microbial risk assessments.

ORD has supported issues related to distribution systems and the Total Coliform Rule. ORD has reviewed white papers developed by OGWDW and industry to address possible health risks associated with distribution systems. ORD also participated in OGWDW's distribution systems exposure assessment workshop. For the Lead and Copper Rule, ORD is providing support for corrosion problems resulting from a shift in treatment and/or disinfection practices.

LTG 2

For LTG 2, there is an array of new tools. QSARs are used to protect public health based on chemical classes of compounds. Omics and computational techniques help increase understanding of a contaminant's mode of action. DNA microarrays address microbial contamination and advanced molecular techniques in support of CCL decisionmaking. NERL provides the means to measure and identify emerging contaminants and compliance monitoring tools if positive regulatory determinations are made.

Mr. Oshida concluded his presentation by summarizing the program's future needs. Additional work is needed on arsenic; DBPs; distribution systems; the Total Coliform Rule; corrosion control, particularly with simultaneous compliance; measures to assess progress in preventing waterborne disease; and data gathering for the 6-year reviews.

RELEVANCE OF ORD'S DRINKING WATER RESEARCH PROGRAM
STATE AND LOCAL PERSPECTIVE
Mr. Anthony Bennett, State Regulator, Texas Commission on Environmental Quality, Water Supply Division

Mr. Bennett presented a state and local perspective of the DWRP. He began by explaining that the states delegate many responsibilities to local governments and health departments. State responsibilities fall under the Public Water System Supervisory Program. Under an agreement called state primacy, states do not enforce federal regulations; however, they must adopt their own regulations that are no less stringent than the federal regulations. States also must take timely and appropriate enforcement action against violators.

Support from state leaders is important. This includes agency management and elected state and local officials. It also is important to have convincing data on health effects to demonstrate that the monitoring data are reliable.

The Texas Commission on Environmental Quality uses EPA's regulations. From a public and environmental health perspective, the Commission is conducting risk assessment, risk management, and risk communication. Good scientific data support the ability to do this; detecting hazards and determining exposure cannot be simply a political decision. The Commission must have effective monitoring and data collection procedures; sound data are necessary for making accurate assessments and determining compliance with regulations.

There are several ways to manage risk when a problem occurs in a water system. If the problem occurs in the source, the source can be removed or the water can be treated to remove or reduce exposure. To make a convincing argument for a particular treatment, one must demonstrate feasibility, technical efficacy, and affordability. The technology to remove a contaminant is not always affordable. In addition, lag time exists between the implementation of a new rule and the commercial availability of the technology to address it. NRMRL provides relevant information through publications, workshops, and demonstrations. A workshop is planned for August 16-18, 2005, in Cincinnati, Ohio, on the topic of arsenic removal from drinking water. Vendors will demonstrate arsenic removal technologies to state regulators and others.

In the area of emerging contaminants, the UCMR and CCL are important to consider. In Texas, there is a large amount of naturally occurring perchlorate. Currently, a national MCL has not been set for this chemical. If an MCL is set under the SDWA, the state will default to that MCL because it is a rigorous standard.

Questions and Answers

Dr. Sedlak asked if there were areas that were important to Texas, but were not covered under the SDWA or the LTGs (e.g., water reuse). Mr. Bennett replied that when the Total Coliform Rule was reevaluated, *Legionella* was removed from the list. He recommends that it be returned to the list. Currently, *Legionella* is handled under the Surface Water Treatment Rule; however, that rule covers source water, and *Legionella* was determined to be a recontamination of the

distribution system. Mr. Bennett suggested developing an efficient process for returning contaminants to the CCL or reallocating resources to address issues that emerge suddenly.

RELEVANCE OF ORD'S DRINKING WATER RESEARCH PROGRAM HOMELAND SECURITY PERSPECTIVE

Mr. Kim R. Fox, Acting Division Director, Water Infrastructure Protection Division National Homeland Security Research Center (NHSRC), ORD, EPA

Mr. Fox began his presentation with an overview of EPA's NHSRC. The Center was set up initially as a 3-year temporary program in response to the events of September 11, 2001. Originally, NHSRC had no laboratory facilities; all research was contracted out. This past December, however, the Center was made a permanent part of ORD.

NHSRC's mission is to understand the terrorist threat, communicate the risks, and restore contaminated areas safely. This includes providing state-of-the-art scientific knowledge and technology to emergency responders, building owners, water utility operators, health departments, and others to enhance their ability to detect contamination quickly, respond effectively, and restore contaminated areas safely. Homeland Security Presidential directives state that EPA is the water sector lead for all issues concerning water security. EPA also was designated as the lead in cleaning up after a terrorist attack.

NHSRC's initial endeavor was to allocate resources to provide the maximum protection. The next effort was to evaluate the threat of intentional contamination. The Water Security Research and Technical Support Action Plan was developed jointly with OW and ORD to address the vulnerabilities of drinking water and wastewater infrastructures (i.e., physical, cyber, and contamination threats). Extensive input was provided by stakeholders, and the plan was reviewed by the NAS. In developing the plan, several key research and technical support needs were identified, including:

- ✧ Methods for detecting and monitoring contaminants in water.
- ✧ Rapid screening technologies.
- ✧ Contamination monitoring systems for distribution and collection systems.
- ✧ Methods to test and evaluate technology performance.

Mr. Fox elaborated on several of these needs. For example, how can EPA determine if water is being contaminated intentionally? If a terrorist claims to have contaminated the water system, how can EPA evaluate the veracity of the claim? How can unknown contaminants be screened? How can they be detected in distribution or collection systems? How would EPA clean up after an attack, and how can cleanup technologies be tested? Mr. Fox added that approximately 9,000 vendors claim to have products for homeland security; however, only a small percentage of these claims are valid.

NHSRC's key research and technical support projects include:

- ✧ State-of-the-art reviews of contamination warning systems (i.e., for water that has been contaminated).
- ✧ A state-of-the-science review of emerging detection and monitoring technologies at EPA's T&E facility.
- ✧ A performance review of typical water quality monitors and sensors.
- ✧ Protocol development for concentrating and analyzing water for microorganisms (this is particularly difficult if the microbe is not distributed widely).
- ✧ Testing and evaluation of the performance of monitoring, treatment, and decontamination technologies (i.e., for organisms that typically are not thought of as being in water—surrogates can be used in laboratories).

A Presidential pilot program, Water Sentinel, could involve placing sensor devices into distribution systems across the country; however, Congress may determine that this is not a priority for this fiscal year.

Currently, technologies do not exist to identify every contaminant instantly. The technologies indicate that an event has occurred. Scientists then determine the abnormality in the water system. In the early 1980s, a water system near Pittsburgh was contaminated; an individual intentionally pumped a quart of a contaminant into a distribution system. In that situation, the local community tried for 9 months to clean the contaminant out of the pipes and residences. Ultimately, some pipes and components had to be replaced. This would be a massive and costly undertaking in a location such as New York City. Therefore, research on removing chemicals from contaminated water is being conducted at NHSRC and the T&E facility.

RELEVANCE OF ORD'S DRINKING WATER RESEARCH PROGRAM
RESEARCH PARTNER PERSPECTIVE
Mr. Richard Karlin, Deputy Executive Director, AwwaRF

Mr. Karlin began by acknowledging EPA's role in establishing the AwwaRF. The foundation started as a 3-year cooperative agreement with EPA, with $1 million in seed money matched by industry. Since then, AwwaRF's budget has increased to $37 million.

The AwwaRF used to be the American Water Works Association and Research Foundation; however, it dropped the American Water Works Association component. The members primarily are water utilities throughout the world (90 percent in North America). Their mission is to advance the science of water to improve the quality of life. This is accomplished by sponsoring research (i.e., research is not done internally; the foundation collects funds and farms out the work to other organizations); developing knowledge (i.e., distilling raw information to usable knowledge); and promoting collaboration. AwwaRF works with 30 different partners, primarily national organizations.

The foundation's strategic goals are to: be an efficient and customer-responsive organization, provide environmental leadership in the areas of watersheds and disposable residuals, and support efforts to ensure high-quality water and reliable infrastructure.

AwwaRF has conducted more than 800 research projects; 219 of them have been in collaboration with EPA (i.e., DBP council, health effects of arsenic with California water utilities, and perchlorate). The Research Advisory Council develops AwwaRF's research agenda each year. There are four work groups, each with an EPA representative. Issue Planning Groups design research agendas related to infrastructure. EPA is involved closely in this work. Each project has peer review experts from various organizations. To date, 173 projects have had Project Advisory Committee members from EPA, and 81 different people from the Agency have served on Project Advisory Committees. AwwaRF has collaborated with EPA in many areas unrestricted by Congress, including:

- ✧ *Giardia*
- ✧ Sludge (i.e., residuals)
- ✧ Filtration
- ✧ Intrusion
- ✧ Ground water virus occurrence
- ✧ EDCs
- ✧ UV integration
- ✧ DBPs
- ✧ New bugs
- ✧ New methods.

The Disinfection Byproduct Council is the only council that has been delegated funding authority by the foundation's Board of Trustees. Several epidemiological studies were conducted, including the David Savage study (i.e., an effort to reproduce the California study on reproductive endpoints). Several partnerships also were established to address arsenic, perchlorate, and homeland security. These partnerships foster cooperation in the industry, avoid redundancy in research, leverage resources, provide mutually supportive results, exchange knowledge, and provide technical guidance. One such partner, the Global Water Research Coalition, is comprised of 13 organizations, representing 9 countries and 4 continents. The Global Water Research Coalition exemplifies EPA's involvement globally in the area of protecting drinking water.

Questions and Answers

Dr. Ward asked if EPA representatives serving on the Project Advisory Committee are from the DWRP and if they participate in reviewing proposals. Mr. Karlin affirmed that they are primarily from the DRWP; some are from OW, but most are from ORD. They also are involved in proposal review. Dr. Sayler asked if there was any Asian participation. Mr. Karlin replied that there was none.

ORD WRAP-UP COMMENTS
Dr. Greg Sayles, Acting NPD, DWRP, ORD, EPA

Dr. Sayles thanked the participants and members of the Subcommittee. He explained that the intent of the meeting was to focus on written materials, oral presentations, and posters to familiarize the Subcommittee with the DWRP outcomes. He mentioned that the materials distributed to the Subcommittee included a table of charge questions. Dr. Sayles also thanked

Ms. Coates and Ms. Lori Kowalski for their work in organizing the meeting, as well as the speakers, poster presenters, theme leads, graphic support staff, and meeting support staff from The Scientific Consulting Group, Inc.

PUBLIC COMMENT
Mr. Richard Johnson, Global Manager, Rohm and Haas Company

Mr. Johnson explained that Rohm and Haas produces organotins. In his position as Global Manager, he works with government agencies worldwide. He attended a meeting in April about organotins with scientists from RTP.

Mr. Johnson related the difficulties his organization has encountered in other areas of the world in trying to discuss organotins. The agencies are receptive to information, but are not eager to discuss it to ensure a full understanding. They provide information only on a selective basis. The organotins present challenges to EPA on many levels. They are part of the water distribution system, but less a part of the ground water. The issues involve mixtures and allowable levels.

Mr. Johnson stated that his company would be happy to collaborate with EPA to address the many chemical/toxicological questions. EPA is creating valuable data for the industry. For example, a study concerning neurotoxicity in newborns raised many industry questions. EPA showed that this study had some significant flaws. Organotins are part of EPA's High Production Volume Challenge Program, and a wealth of toxicological data has been collected. Mr. Johnson added that Rohm and Haas has had a very productive interaction with EPA, for which he thanked the Agency.

Ms. Coates dismissed the Subcommittee members so that they could work in closed session groups of two each, which is allowable under FACA. The groups worked individually until 5:30 p.m.

June 23, 2005

INTRODUCTION
Dr. Gary Sayler, Chair, Drinking Water Research Subcommittee

Dr. Sayler announced that the objective for the morning was to continue the summation. Later, the Subcommittee would split into groups to continue writing.

Dr. Sayler explained that he was developing summation thoughts for the outbriefing. This will not be a complete, detailed report. The Subcommittee will produce a report that is submitted to the BOSC for review and approval. The BOSC will provide the final report to ORD. The outbriefing will include general impressions of the meeting and an overview of the Subcommittee's review and analysis; it will not provide any recommendations or any definitive conclusions.

Dr. Ward asked about the process of putting together the CCL 2, particularly the required documentation. Does ORD complete the documentation, and is it available to the public? Dr. Hauchman explained that questions about how the list was generated and risk classification arise whenever CCL research issues are discussed. Nine decisions were made; all were negative determinations. OW has the lead for publishing the list in the *Federal Register* and generating background documentation for the docket. ORD supports that effort. The information is available from OW and the docket.

Dr. Ward asked about the process for expert reviews and regulatory determination. Dr. Hauchman explained that OW leads the process. There is a universe of chemicals (the Preliminary Contaminant Candidate List), followed by a smaller list. The process involves expert review and is convened by OW. ORD is not at that stage yet; we are preparing for a detailed briefing and participating in work groups. ORD will work with OW, but we do not know the details. Dr. Sayles asked if Dr. Ward meant ORD's involvement in those steps or a detailed timeline. Dr. Ward replied that the timeline seems to be laid out clearly; she asked where ORD fits into the process. Dr. Hauchman answered that ORD is involved in a work group process. OW leads with technical support from ORD.

Dr. Ward asked about the health risk assessment part, which did not seem to be developed as well—understandably because it required screening methods and information. She added that the plan is to include the epidemiology group, review the literature, and develop a database of available studies. Dr. Hauchman asked if she meant a risk assessment that supports a regulatory determination or a CCL listing. Dr. Ward answered that she meant a regulatory decision. Dr. Hauchman explained that OW has the lead, but in some cases ORD leads in preparing a risk assessment. In either case, particularly when ORD has the lead, there are technical advisors. ORD reviews the assessment and ensures that the health of people are involved. ORD has to sign off on these regulatory decisions, which means they must concur with the assessment. This is handled at the highest level in ORD, so it has to reflect ORD scientific input.

Dr. Raymer asked when the next review of the list will occur, and how the timing of that review aligns with OW receiving ORD's research results to support the decisions. Dr. Hauchman explained that the reviews take place on a 5-year cycle. CCL 2 was published in 2004. Dr. Hauchman said that the new cycle begins 4 or 5 years from now, but the negotiations with OW about research needs are ongoing. OW has scheduled a briefing about the CCL for OW and ORD staff; Dr. Hauchman expects the CCL work to be renewed. There are no changes between CCL 1 and CCL 2. ORD can focus on the contaminants that currently are on the list for the next round of regulatory determinations. The contaminants for future CCLs are to be determined.

Dr. Sedlak commented that it is a moving target, particularly for those involved in treatability studies. It is difficult to plan research when the priority contaminants keep changing. Dr. Hauchman replied that many contaminants are considered, not just those that are on the list. Dr. Goodrich added that ORD also is working on EDCs and pharmaceuticals. OW is providing input about what they foresee as the next priority items, which will be included in the next MYP. Immediately following this program review meeting, there will be a meeting to focus on the Drinking Water MYP and potential projects for 2007, 2008, 2009, and beyond. Through these efforts and discussions at other national meetings, ORD is trying to anticipate probable items for

CCL 3. Dr. Hauchman agreed that ORD is trying to be proactive by focusing beyond OW's immediate concerns. Current work addresses pathogens that are not on CCL 2 (e.g., *Legionella* and *Hepatitis E*), and treatment studies are ongoing for chemicals that are not on the list (e.g., pesticides, Teflon®, and Freon).

Dr. Sedlak asked about the fact that the analytical expertise and the treatment expertise reside in different locations. He noted that some communities' pathogens and contaminants cannot be tested on certain equipment. Does this cause limitations or affect what ORD chooses to study? Dr. Goodrich explained that certain surrogates and other indicators are used. The scientists working on organotins are in Cincinnati. NRMRL has been conducting blind studies.

Dr. Sayles added that he was involved in the capital equipment acquisition process at NRMRL. He explained that ORD does not have a large budget for new, high-end equipment. The laboratories and centers cooperate; every laboratory does not need to have every piece of equipment. ORD is trying to have an effective capital equipment strategy, but resources are limited.

Dr. Hauchman asserted that the core of the analytical capability in the water program is in Cincinnati, although some work is conducted at separate laboratories. The Athens, Georgia, laboratory also is available.

Dr. Sedlak asked if there were any institutional barriers (e.g., if analytical chemists develop methods but are not there to run samples for research programs). Does NRMRL view itself as a methods development laboratory and not a service laboratory for research projects?
Dr. Hauchman replied that there were no institutional barriers for collaboration. The scientists participate in research and do not function as a "job shop." Dr. Goodrich agreed that the scientists participate as co-authors and mentioned the *Cryptosporidium* methods development as an example. Dr. Sedlak responded that his impression, based on discussions with younger investigators, was that those scientists with access to high-end equipment develop high-end methods and do not want to help other laboratories. Regarding the subjects of the research, he described his observation with the adage, "if all you have is a hammer, everything looks like a nail."

Dr. Ward asked about the allocation of resources for research versus regulated contaminants.
Dr. Sayles explained that the emphasis is roughly equal, but it is shifting from LTG 1 to LTG 2.
Dr. Hauchman added that surface water and ground water rules receive less emphasis now. He also noted that workforce realities limit the programs' ability to address new issues. For example, a workforce of cancer toxicologists who have focused on DBPs for 10 or 15 years cannot become reproductive toxicologists instantly. Tools such as the grants program, extramural projects, and cooperative agreements offer more flexibility.

Dr. Sayler asked if more of the STAR Program resources were dedicated to LTG 2 than LTG 1.
Dr. Hauchman replied that he thought they were. Dr. Sedlak asked if Dr. Christine Moe's STAR ground water study would be characterized as a CCL. Dr. Hauchman answered that it is difficult to pigeonhole research. The work is under the surface water/ground water rule in the MYP, but it has a different angle. Dr. Sedlak asked if it was a multimillion-dollar study; he thought it was

only a 3-year study. Dr. Hauchman replied that negotiations are underway with the AWWA. Dr. Sedlak asked if the STAR Program required projects to be completed in 3 years, because it seems like a challenge to conduct an epidemiology study with 3-year funding. Dr. Hauchman answered that he did not know.

Dr. Sedak commented that Dr. Hauchman's handouts were very helpful. He asked about items in LTG 2 that appeared to be outputs rather than outcomes. Dr. Hauchman explained that the CCL program involves the output stage primarily. Dr. Sayler added that the outcomes could be delayed for several years. Dr. Sedlak asked if there were any documents that OW could use in making regulatory determinations. Dr. Ward suggested that the nine regulatory determinations and CCL 2 could be considered outcomes. Dr. Hauchman agreed that they were outcomes, but cautioned against describing ORD's products as influencing the determinations. The decisions were made primarily for contaminants on the regulatory determination list, for which additional research generally is not needed. Dr. Ward asked whether the DWRP scientists provided the data to make the decisions. Dr. Hauchman answered that the decisions for the first round were based on published literature, not on in-house research. He added that there was a certain robustness to the existing scientific database.

Dr. Sedlak noted that quantifying outcomes is inherently challenging. The impact of ORD's decisions might not be apparent for a long time. Dr. Sayles agreed that quantifying outcomes is difficult, and the appropriate process will require much thought. Dr. Sayler recommended including this issue in the report.

Dr. Johnson referred to the logic diagram; the outcomes are achieved by OW. The DWRP should provide information outputs to support the outcomes. Unlike other programs, the DWRP connects so closely to OW that each program's success depends on the other. The DWRP's outcomes are produced through OW. Dr. Sayles concurred, but added that the CCL involves a time delay. Dr. Johnson commented that, irrespective of the time delay, the program should be able to demonstrate past performance and suggest future improvements. Dr. Sayles noted that the 6-year review has known research requirements. In addition, the rule will be on the docket. It is not known what contaminants will be selected, what will be published, or for what purpose the work will be used. The definition of the word "use" could be broadened, but the program must be quantifiable for OMB, and that is a challenge. Dr. Hauchman added that parts of the CCL program can be measured. The analytical methods are one kind of outcome. Data on special, high-visibility chemicals, such as perchlorates, represent important outputs from the program.

Mr. Bennett commented that researchers use different analytical approaches. He recommended using an approval process to ensure consistency instead of having the work cross-checked by three or four separate laboratories. Mr. Bennett also noted that OW met its Congressional requirement by making decisions on at least five contaminants. He added that items left over from CCL 1 are carried over to CCL 2, and decisions can be made before the end of the 5-year cycle. From a regulatory standpoint, this continuum is important, particularly for emerging contaminants.

Dr. Sayler announced that some additional information had been provided to the Subcommittee on the previous day. Peer review information was distributed that morning, followed by the STAR Program's selection of proposals for awards. A response to the Subcommittee's inquiry about intramural research prioritization was distributed as well.

Ms. Coates asked how much DWRP funding goes to each laboratory. Dr. Sayles answered that he is working on that with the budget office and he will provide that information when it is available.

Dr. Sayler asked the Subcommittee members to return to their work groups and begin drafting the report.

OUTBRIEFING
Dr. Gary Sayler, Chair, Drinking Water Research Subcommittee

The Subcommittee members returned at 1:00 p.m. for a report out of the draft findings. Dr. Sayler announced that this outbriefing would be short because most of the Subcommittee members had to leave soon. Ms. Coates asked those participating by telephone to identify themselves. The participants included: Michael Broder, Karl Jensen, Bruce Mintz, Angela Page, Susan Richardson, Jane Ellen Simmons, Candida West, Richard Wiggins, and Douglas Wolf.

Dr. Sayler explained that the BOSC Executive Committee will review the Subcommittee's report before it is finalized. Most of the present meeting's observations will be generalizations because they are not BOSC-approved. The BOSC is an independent advisory committee offering guidance and information to ORD on its research programs. The BOSC has a great deal of independence and latitude on what it can and will say. The Subcommittee is charged with examining the DWRP and providing advice and comment to ORD. The objective is to review and evaluate the program's relevance, utility, performance, and scientific leadership.

The Subcommittee was given a series of charge questions related to the relevance, design, and progress in addressing science and client needs; scientific quality and leadership of the program; and coordination and communication with OW, other EPA offices, the scientific community, and stakeholders. The Subcommittee's response to these questions will be used by OMB in the PART process as well as by ORD.

Dr. Sayler provided a brief summary of the Subcommittee's overall findings. The DWRP provides high-quality research of national importance that supports OW's and EPA's strategic goals. The research projects appear to be consistent with the MYP. Excellent progress has been made in the area of regulated contaminants.

Some Subcommittee members are uncertain about incorporating source water and distribution systems into LTGs 1 and 2 rather than keeping them in a separate third goal. Dr. Sedlak commented that this concern did not represent a fully formed view or a consensus; however, he presented reasons against folding the topics into LTGs 1 and 2. First, there might not be a good scientific basis for doing so. For example, distribution system issues can transcend both LTG 1 and LTG 2. Some of the research showed CCL pathogens residing in the distribution system; to

lose that focus on the distribution system might lose some of the science that goes with it. Moreover, the emphasis on issues related to distribution systems and source waters is increasing. To fold them into LTG 1, which is becoming a lower priority, and to make them ancillary in LTG 2 might hinder the progress. There might be some merit, therefore, in leaving them as a separate LTG 3. This will be considered in the report. Dr. Sayler added that water reuse is another issue that is expected to increase in importance and should be considered in the report.

Dr. Sayler summarized the discussion on scientific leadership. The Subcommittee distinguished between leadership in general science, both nationally and internationally, and the leadership of individual researchers in ORD. Programmatically, the past scientific leadership has been very good. The question is how sustainable it will be. The Subcommittee agrees that it will be sustainable, but perhaps in isolated pockets that are defined by the constraints and mandates of the SDWA. Without sufficient resources or latitude to pursue every important issue, the program is confined to those areas that do have the resources and the mandate. The Subcommittee also agreed that researchers in ORD demonstrate strong leadership, individually and as a unit.

Dr. Ward commented that research progress has been excellent for regulated contaminants, but excellent progress also has been made on the CCL contaminants, particularly on the development of analytic methods in a quick, responsive fashion. Dr. Sayler added that such progress goes hand in hand with the scientific leadership.

Dr. Sayler stated that ORD's research outputs lead to important outcomes, both with respect to OW and other clients. There is a need to increase ORD's visibility in this area and to enhance the metrics of research contributions and communication. The Subcommittee will try to offer concrete suggestions in the report.

Dr. Hauchman asked Dr. Sayler to elaborate on his comments about sustainability and isolated pockets. Dr. Sayler explained that EPA in general, and ORD in particular, do not appear to maintain the leadership role they held several years ago, nationally or internationally. Resource issues sometimes are the drivers. For example, some states can devote almost more resources to these issues than ORD can, in terms of actual dollars. In such situations, others will begin to take the lead. In the area of EDC research, western Europe probably is the leading force now. Whether EPA should be the driving force is a resource issue. The Agency is not anticipated to maintain the same level of broad, sustained excellence that it held in the past. It will, however, continue to lead the science in areas for which it has resources and mandates to do the work. The DWRP does excellent, high-quality work. It has good scientists, including those in the STAR Program, and high-quality work drives the science. EPA still is anticipated to have important contributions nationally and internationally. It probably will continue its leadership role in bringing people together, developing consensus, and moving science forward, but it will not be as easy as it was in the past.

Dr. Sayler thanked the Subcommittee members and the other participants, and adjourned the meeting at 1:30 p.m.

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Other Attendees

Mr. Anthony Bennett
State Regulator
Texas Commission on Environmental Quality

Denise Hoffman
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Mr. Richard Johnson
Global Manager
Rohm and Haas Company

Mr. Richard Karlin
Deputy Executive Director
American Water Works Association Research
Foundation

Lisa Sutter
The Scientific Consulting Group, Inc.

APPENDIX

Conference Agenda

B • O • S • C

U.S. EPA BOARD OF SCIENTIFIC COUNSELORS
Drinking Water Subcommittee

DRAFT MEETING AGENDA
June 21-23, 2005

U.S. Environmental Protection Agency
Office of Research and Development
Andrew W. Breidenbach Environmental Research Center
26 W. Martin Luther King Drive
Cincinnati, Ohio

Presentations and Discussions in the Auditorium
Poster Sessions in the Annex Atrium

TUESDAY, JUNE 21, 2005

8:00 a.m.	Registration	
Welcome and Overview		
9:00 a.m.	Opening Remarks Introductions, Agenda	Dr. Gary Sayler Chair, DW Subcommittee
9:15 a.m.	DFO Welcome and Charge	Ms. Edith Coates Designated Federal Officer, ORD
9:30 a.m.	ORD Welcome	Dr. William Farland Acting Deputy Assistant Administrator for Science, ORD
9:40 a.m.	Introduction to the Drinking Water Research Program	Ms. Sally Gutierrez Acting Laboratory Director, NRMRL
10:00 a.m.	Overview of the Drinking Water Research Program	Dr. Gregory Sayles Acting National Program Director, ORD Drinking Water Research Program
10:45 a.m.	Break	

Long-Term Goal 1 - *Research Supporting Agency Decisions on Regulated Contaminants*

11:00 a.m.	Overview of Long-Term Goal 1 Research	Dr. James Goodrich Acting Director, Water Supply and Water Resources Division, NRMRL
11:30 a.m.	Lunch	
1:00 p.m.	Long-Term Goal 1 Poster Session 1 (Arsenic and SW/GW Pathogens)	ORD Presenters
2:30 p.m.	Poster Discussion	DW Subcommittee
3:00 p.m.	Break	
3:15 p.m.	Long-Term Goal 1 Poster Session 2 (Disinfection By-Products and Distributions Systems)	ORD Presenters
4:45 p.m.	Poster Discussion	DW Subcommittee
5:15 p.m.	Adjourn for the Day	

WEDNESDAY, JUNE 22, 2005

9:00 a.m.	Review of Yesterday's Activities Overview of Today's Agenda	Dr. Gary Sayler Chair, DW Subcommittee

Long-Term Goal 2 - *Research Supporting Agency Decisions on Unregulated Contaminants*

9:15 a.m.	Overview of Long-Term Goal 2 Research	Dr. Fred Hauchman Acting Director, Microbial and Chemical Exposure Assessment Research Division, NERL
9:45 a.m.	Long-Term Goal 2 Poster Session	ORD Presenters
11:45 a.m.	Poster Discussion	DW Subcommittee
12:30 p.m.	Lunch	

Relevance of the Drinking Water Research Program to Program Offices, States, and Research Partners

1:30 p.m.	Office of Water Perspectives	Dr. Ed Ohanian Director, Health and Ecological Criteria Division, OST, Office of Water
1:50 p.m.	Office of Water Perspectives, Continued	Mr. Phil Oshida Acting Director, Standards and Risk Management Division, OGWDW, Office of Water
2:10 p.m.	State and Local Perspective	Mr. Anthony Bennett Texas Commission on Environmental Quality
2:30 p.m.	Homeland Security Perspective	Mr. Jonathan Herrmann Acting Deputy for Management, National Homeland Security Research Center
2:50 p.m.	Research Partner Perspective	Mr. Richard Karlin Deputy Executive Director Awwa Research Foundation
3:10 p.m.	ORD Wrap-Up Comments	Dr. Gregory Sayles
3:30 p.m.	Public Comment	
3:45 p.m.	Working Time for Panel	DW Subcommittee
5:30 p.m.	Adjourn for the Day	

THURSDAY, JUNE 23, 2005

9:00 a.m.	Working Time for Panel	Drinking Water Research Subcommittee
2:00 p.m.	Report Out of Draft Findings	Dr. Gary Sayler Chair, DW Subcommittee
3:00 p.m.	Adjourn	